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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,674	08/08/2006	Muthunadar P. Periasamy	1667 WO/US	4628
7590	07/07/2010		EXAMINER	
Kenneth D Goetz Mallinckrodt Inc 675 McDonnel Boulevard P O Box 5840 St Louis, MO 63134				SAMALA, JAGADISHWAR RAO
		ART UNIT	PAPER NUMBER	1618
		MAIL DATE	DELIVERY MODE	07/07/2010 PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,674	PERIASAMY ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7, 10, 11 and 13-20 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-7, 10, 11 and 13-20 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/28/2006</u> . | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Applicant's election with traverse of Group I claims 1-20, in the reply filed on 05/26/2010 is acknowledged. The traversal is on the ground(s) that US 5,695,742 does not disclose a triiodo-substituted dimers that contains at least one primary amide, and also rejoin the claims of group II, given that there is essentially no additional search burden. This is not found persuasive because US Pat. 5,595,742 teaches compositions, comprising mixtures of non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (II) contrast agents useful for x-ray imaging of human body. Further, searching all of the claims would require searching in numerous different classes and subclasses, as well as a different searching focus depending on whether the product or processes are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made **FINAL**.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/28/2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

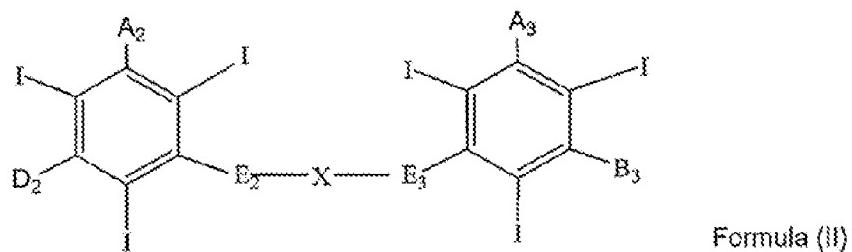
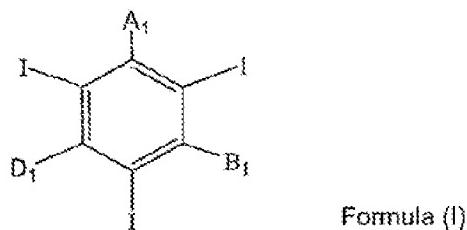
USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

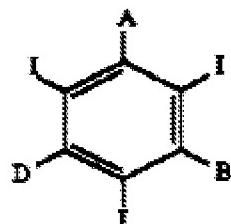
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-7, 10-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (US 5,695,742) in view of Sovak (US 5,698,739).

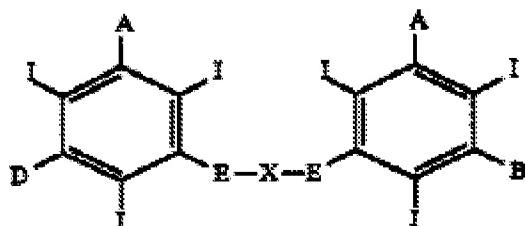
Claims are drawn to an injectable radiological composition for x-ray visualization during radiological examination, the composition comprising a mixture of at least one monomer and at least one dimer corresponding to formula I and formula II



Felder teaches a injectable aqueous compositions, comprising mixtures of non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (II) contrast agents useful for x-ray imaging of human body (abstract and col. 4 lines 30-60).



type (I)



type (II)

Monomer is ioversol and dimer includes contrast agent like iodixanol, iotrol, iotasol. The performance of the compositions is increased by the addition of a series of additives, particularly stabilizers, agents controlling the dissolution, buffers (TRIS) or also biologically acceptable mineral salts like phosphates, tromethanol, EDTA, EDTA CaNa₂, heparin, hirudin, glycerol and the like (col. 9 lines 52-65+). Additional disclosure includes that injectable aqueous compositions comprising mixtures of non-ionic

iodinated aromatic compounds monomer of type (I) and dimmers of type (II), not only have an intermediate osmolality compared to the pure solutions of (I) and (II), and are also isoosmolol or isotonic to the plasma but they also have a lower viscosity than the expected, and a lower toxicity than those shown by the corresponding pure solutions of (I) and (II).

Felder fails to incorporate specific dimer of formula (II) i.e., iosmin (also known as iosimanol).

Sovak teaches non-ionic contrast media and formulations for x-ray imaging procedures. The contrast media have the general formula shown in Figure 1 (col. 2), and may be a dimeric compound, i.e. malonic acid bis-[{3-N-(2,3-dihydroxypropyl-carbamoyl)-5-carbamoyl}-2,4,6-triido-N-(2,3-dihydroxypropyl)anilide, (col. 3 lines 26 - 29), which has the same chemical structure as iosimanol. The compositions are formulated in an aqueous medium, which includes a chelated calcium salt (e.g. EDTA) and a buffer to provide a pH in the range of about 6.5 to 7.5, where the buffer includes tris, citrate, carbonate, or combinations thereof (col. 3 lines 46- 48). Additionally, the compounds are used for radiographic examination and have good biological tolerance (col. 6 line 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate non-ionic iodinated aromatic compounds dimmer formula (II) into Felder's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Sovak teaches that the compounds of formula (II) are stable in aqueous solutions; they readily form

supersaturated solutions which also remain stable. The compounds have good biological tolerance and high iodine content, particularly as compared to presently available non-ionic radiographic contrast agents. Therefore, one of ordinary skill in the art would have a reasonable expectation of success because both Felder and Sovak teaches a injectable aqueous compositions, comprising mixtures of non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (II) contrast agents that can be used in the same field of endeavor such as water-soluble contrast media for the visualization of the urine excretory and cardiovascular systems, and body cavities and for general contrast enhancement in computerized tomography.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618